K110763 (1/1)

510(k) Summary of Safety & Effectiveness

Pursuant to CFR 807.92, the following 510(k) Summary is provided: APR 1 1 2011

1. (a)	**Submitter Address:**	George J. Hattub MedicSense, USA 291 Hillside Avenue Somerset, MA 02726 www.medicsense.com
1. (b)	***Manufacturer Address:***	T.A.G. Medical Products D. N. Ashrat Kibbutz Gaaton 25130, Israel
	Mfg. Phone:	Tel.: 972-3-647-4840
	Contact Person:	Dan Moor
	Date:	March 14, 2011
2.	***Device & Classification Name:***	Bone Fixation Screw, class II device (product code HWC). Latarjet Cortical Screw Set
3.	***Predicate Device:***	The Latarjet Cortical Screw Set K083096 & K091694
4.	***Description:***	The Latarjet Cortical Screw Set consists of an implantable fixation screw which is used for fixation of bone grafts or bone fragments to cortical bone in shoulder surgeries. The fixation screws are offered in the following overall range of length: 20mm – 48mm. (*features- other than the overall length- are identical on all*). The set also includes a threaded bushing which attaches to the proximal end of the fixation screw. Its purpose is to position the screw firmly and safely during the fixation procedure. The bushing is provided in one size. The fixation screw and bushing are supplied in either in Titanium alloy or Stainless Steel. The Latarjet Cortical Screw Set is supplied non-sterile, for single patient use.
5.	***Intended Use:***	The Latarjet Cortical Screw Set is intended to provide the orthopedic surgeon a means of bone fixation and to assist in the management of fractures and reconstructive surgeries.
6.	***Comparison of Technological Characteristics:***	With respect to its indication for use, the Latarjet Cortical Screw Set is substantially equivalent to its predicate device in that it intended for the same clinical purpose. With respect to technology, the design is similar as confirmed by comparison, and the performance is the same as verified by validation. Based upon this, T.A.G. Medical Products believes that its device is safe and effective because it performs the same function in the same manner.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

T.A.G. Medical Products Corporation, Ltd.
% MediSense, USA
Mr. George J. Hattub
291 Hillside Avenue
Somerset, Massachusetts 02726

APR 11 2011

Re: K110763
Trade/Device Name: Latarjet Cortical Screw Set
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: March 16, 2011
Received: March 18, 2011

Dear Mr. Hattub:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K110763(1/1)

Indications for Use

510(k) Number (if known):

Device Name: Latarjet Cortical Screw Set

Indications For Use: The Latarjet Cortical Screw Set is intended to provide the orthopedic surgeon a means of bone fixation and to assist in the management of fractures and reconstructive surgeries.

Prescription Use __x_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110763